UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,378	02/26/2004	Sergey A. Axenovich	5189-2	5322

22442 7590 04/13/2006

SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,378	AXENOVICH ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions/Species

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, and 4-11, drawn to a method for identifying a compound for inducing apoptosis, classified in class 435, subclass 7.1.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 1: as each polypeptide represents an independent invention, not a species.)

II. Claims 1, 3, 13, and 14, drawn to a method of identifying a compound that inhibits growth of tumor cells, classified in class 435, subclass 6.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 1: as each polypeptide represents an independent invention, not a species.)

III. Claims 1 and 12, drawn to a method of identifying a compound for inducing apoptosis by determining the three dimensional structure of a target and a putative inhibitor, classified in class 435, subclass 4.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 1: as each polypeptide represents an independent invention, not a species.)

IV. Claims 15 and 16, drawn to a method for inducing apoptosis, classified in class 435, subclass 375.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 15: as each polypeptide represents an independent invention, not a species.)

V. Claims 17-19, 23-30, 32, and 33 drawn to a method for diagnosis of a tumor in a patient by detecting biomarker mRNA transcription in a test sample, classified in class 435, subclass 6.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 17: as each polypeptide represents an independent invention, not a species)

VI. Claims 17,20, 21, 23-31, 32, and 33 drawn to a method for drawn to a method for diagnosis of a tumor in a patient by detecting biomarker protein or activity in a test sample, classified in class 435, subclass 7.1.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 17: as each polypeptide represents an independent invention, not a species)

The inventions are distinct, each from the other because of the following reasons:

The restriction of the proteins labeled with the given SEQ ID NOS in Groups I-VI as independent inventions is proper. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. The inventions are unrelated because each SEQ ID NO denotes a distinct protein. It is the structural differences engendered by differences in the primary amino acid sequence that give each protein its unique function within

the cell. It is unlikely that any two proteins, even those that are very homologous, have the exact same structure and function. For example, even single amino acid changes in proto-oncogenes can alter protein structure and function in a way to make them oncogenic. Thus, proteins of Groups I-VI are independent inventions. Since the products are unrelated searching all of the claims of both groups would invoke a burdensome search of both the patent and non-patent literature.

The inventions of Groups I-VI are materially distinct methods each from the other, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Groups I-VI involve different steps and/or objectives. For example, Group I drawn to identifying a compound for inducing apoptosis has the unique step of assessing the ability of an inhibitor to induce apoptosis in a cell. Group II has unique objective and steps to assess the ability of a compound to inhibit tumor cell growth. Group III, drawn to identifying a compound for inducing apoptosis, has the distinct steps of determining the three-dimensional structure of a target and the three-dimensional structure of a putative inhibitor of the target. Group IV has the unique objective of inducing apoptosis and the distinct step of inhibiting the expression or activity of a gene. Group V, drawn to a method for the diagnosis of a tumor in a patient, has the distinct step of detecting a biomarker mRNA in a test sample from a patient. Group VI, drawn to a method for the diagnosis of a tumor in a patient, has the distinct steps of detecting a biomarker protein or activity in a test sample from a patient.

Furthermore, searching all of the inventions of Groups I-VI would invoke a burdensome search. Some of the inventions have been classified separately. Thus, each these inventions have

attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. This would necessitate different searches in the patent and or non-patent literature and the consideration of different patentability issues. Although some of the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Elections for Groups I, II, IV, V, and VI

Claims 8, 9, 10 and 11 of Group I are generic to the following disclosed patentably distinct species for "target measurement":

1) measurement by polymerase chain reaction

2) measurement by antibody binding partner

3) measurement by antigen binding partner

4) measurement by determining the amount of product in a biochemical reaction

5) measurement by determining the amount of substrate consumed in a biochemical reaction

Claim 14 of Group II is generic to the following disclosed patentably distinct species for "inhibiting the target in a cell":

1) gene knock-out

2) anti-sense oligonucleotide expression

3) RNAi molecules

4) GSE expression

Claim 15 of Group IV is generic to the following disclosed patentably distinct species:

1) target

2) gene

The products of the above species represent separate and distinct molecules or methods with different structures, functions, or steps such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the **allowance** of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER